

REMARKS

This Amendment is in response to the Office Action dated August 11, 2004. Claims 1-31 were pending in this application. Of those claims, claims 5, 8, 9 and 15-31 were withdrawn from consideration in view of a previous restriction requirement and election of species. By this Amendment, claim 1 has been amended to better define the claimed invention. Dependent claims 2 and 3 have been rewritten in independent form. Claim 2 also has been amended to include the recitation that the mandrel includes a shapeable distal tip. Claim 4 has been amended to indicate the combination of a recovery system with the claimed delivery system of claim 1. Additionally, claim 6 has been amended to dependent from claim 1. Claim 14 has been canceled without prejudice. Previously withdrawn claims 15-31 also have been cancelled without prejudice at this time and will be pursued in a divisional application to be filed later. New claims 32-43 are being presented herein. Applicants have carefully reviewed the arguments presented in the Office Action and respectfully request reconsideration of all of the pending claims in view of the remarks presented below.

Applicants have amended the specification to address the objections raised by the Examiner. First, the title of the invention has been changed to "DELIVERY AND RECOVERY SYSTEMS HAVING STEERABILITY AND RAPID EXCHANGE OPERATING MODES FOR EMBOLIC PROTECTION SYSTEMS." Applicants believe that this provides a more descriptive title as requested by the Examiner. The disclosure also was amended to address the informalities pertaining to the description of FIG. 18. It is believed that these amendments should fully address the Examiner's concerns raised in paragraphs 4 and 5 of the Office Action.

Applicants have amended claim 4 to positively recite the combination of a recovery system with the claimed delivery system of claim 1. Accordingly, there is proper antecedent basis for the recovery system in claim 7. Applicants respectfully request the Examiner to withdraw the 35 U.S.C. § 112, second paragraph rejection of claim 7.

Claims 1, 3, 4 and 7 were rejected under 35 U.S.C. § 102(a) and/or (e) as being anticipated by U.S. Patent No. 6,171,327 to Daniel et al. ("the Daniel patent"). The passage of the Daniel patent relied upon by the Examiner in rejecting the pending claims discloses the use of a slit that extends from the very distal tip of the catheter back to the proximal end. With regard to claim 1, the Daniel patent does not show the use of a port opening in communication with the catheter lumen which allows the guide wire to exit therefrom and extend therethrough to allow the guide wire to remain outside of the main portion of the catheter during delivery. This port opening and the distal portion of the catheter of the present invention create a separate rapid exchange type delivery system which can be used as an alternative delivery platform to the delivery platform created by the extending the guide wire within the length of lumen formed in the catheter. In this regard, the delivery system recited in claim 1 allows the guide wire to be placed within the lumen of the catheter and rapidly removed from the patient's vasculature via the manipulating-enabling element which can be, for example, as recited in claim 11, a slit that extends along the length of the catheter. Alternatively, the port opening and distal portion which form another form of a rapid exchange system that allows only a small portion of the guide wire to extend within the lumen could be used. This type of delivery platform also enhances the ability of the physician to rapidly remove the catheter from the patient's vasculature. This combination of different rapid exchange type platforms are simply not disclosed in the Daniel patent. Applicants, thus submit that the claimed invention of claim 1, along with dependent claims 4 and 7, would be patentably distinct from the Daniel patent.

The Examiner also has rejected claim 3 under § 102 as being anticipated by the Daniel patent. Applicants note that the Examiner believes that the Daniel patent discloses a catheter that includes a tip, the distal end thereof which is adapted to be shapeable by the operator. However, Applicants strongly disagree with this characterization of the Daniel patent. While certain embodiments shown in the Daniel patent do show the use of a distal tip with the catheter, these distal tips are not shapeable distal tips in accordance

with the present invention. The term “shapeable” as used in the art and the present invention denotes a component which can be shaped to create a desired curvature or bend at the distal end that allows the user to steer the catheter through the sometimes tortuous anatomy of the patient. In this regard, the shapeable portion of the catheter must have some rigidity to remain in the shaped configuration to allow the user to torque the catheter as needed to steer the medical device within the vasculature. The use of a shapeable element at the distal tip of the catheter allows the catheter itself to be manipulated at its proximal end by the physician to steer either the catheter alone, or a combination of the catheter and guide wire, within the vasculature. Applicants have carefully reviewed the Daniel patent and submit that the disclosed distal tip in the Daniel patent is not a shapeable tip and that steering feature is nowhere disclosed in the Daniel patent. For example, the distal tip portion shown in FIG. 13 of the Daniel patent utilizes an elastomeric material to allow the tip portion 440 to stretch distally from the opening of the housing 418. As is shown in FIGS. 15 and 16, the distal tip shell 640 is designed to collapse around the wire 626 once the housing 618 is withdrawn from the elastomeric shell 640. For these reasons, elastomeric materials are utilized and disclosed in the Daniel patent. However, the distal tips disclosed in the Daniel patent simply cannot provide the needed rigidity to allow the distal tip to be shaped and remain in a desired configuration for steering purposes. Rather, this distal tip in the Daniel patent must be sufficiently elastic to allow for stretching and collapsing. Accordingly, it is believed that the Daniel patent fails to disclose the invention as defined in claim 3. Applicants respectfully request the Examiner to withdraw the Daniel patent as an anticipatory reference to claim 3.

Claims 2, 6 and 10-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Daniel patent. First, with regard to claim 2, it is noted that claim 2 now recites a mandrel which includes a shapeable distal tip that allows the catheter to be steered through the patient’s vasculature independent from the guide wire. In this aspect of the claimed invention, the mandrel allows the tip portion of the catheter to be shaped to allow the physician to bend the catheter into a desired shape to steer the catheter. This

shapeable distal tip of the mandrel functions like the distal tip discussed above with respect to claim 3. However, the mere fact that the Daniel patent states that the catheter should be made from a material sufficient rigid, yet flexible to be advanced through a tortuous path through the target site, would not lead one skilled in the art to use a mandrel having a steerable tip since the Daniel patent fails to disclose any type of steering which can be performed by the catheter itself. Accordingly, it is believed that claim 2 is patentably distinct from the Daniel patent.

Dependent claims 6 and 10-13 have been amended to dependent from independent claim 1. For all of the reasons addressed above with respect to claim 1, the particular combination of elements recited in these dependent claims are not shown in the Daniel patent. Allowance of these dependent claims is respectfully requested.

The newly presented claims in this Amendment are directed to a structure which includes a portion of a catheter having a port opening and a distal portion adapted to house the embolic protection device in a collapsed, delivery position. As mentioned above, the Daniel patent fails to disclose the use of a port opening and distal portion as a rapid-exchange delivery system. The newly presented dependent claims are directed to a combination of elements which are neither shown nor suggested in the Daniel patent. Accordingly, it is believed that these new claims are patentably distinct from the Daniel patent.

In view of the foregoing, it is respectfully urged that all of the present claims of the application are patentable and in a condition for allowance. The undersigned attorney can be reached at (310) 824-5555 to facilitate prosecution of this application, if necessary.

In light of the above amendments and remarks, Applicants respectfully request that a timely Notice of Allowance be issued in this case.

INFORMATION DISCLOSURE STATEMENT

Applicants wish to bring to the attention of the Patent Office the references listed on the attached PTO/SB/08a, and request that they be considered by the Examiner. This